



Florida Department of Agriculture and Consumer Services
Division of Food Safety

HEMP EXTRACT FOR INGESTION AND INHALATION



HEMP EXTRACT FOR INGESTION AND INHALATION

Section 581.217, Florida Statutes, gives the Florida Department of Agriculture and Consumer Services (FDACS) regulatory authority over Hemp and Hemp Extract intended for Human Consumption. As part of the State Hemp Program, FDACS Division of Food Safety has adopted Rule 5K-4.034, Florida Administrative Code. This rule regulates the sale of Hemp Extract.

1. Definitions

“Hemp” means the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers thereof, whether growing or not, that has a total delta-9-tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry-weight basis.

“Hemp Extract” means a substance or compound intended for ingestion, containing more than trace amounts of cannabinoid, or for inhalation which is derived from or contains hemp, and which does not contain other controlled substances. The term does not include synthetic CBD or seeds or seed-derived ingredients that are generally recognized as safe by the United States Food and Drug Administration (FDA).

“Human Consumption” includes products intended for human Ingestion and/or human Inhalation, as defined below, but does not include external topical dermal applications.

“Ingestion” means the process of consuming Hemp Extract through the mouth, whether by swallowing into the gastrointestinal system or through tissue absorption.

“Inhalation” means the process of consuming Hemp Extract through the mouth or nasal passages into the respiratory system.

2. Is CBD the same as Hemp?

No. Cannabinoids such as Cannabidiol (CBD) are derived from the Hemp plant. Products intended for human consumption containing CBD, other cannabinoids, or containing any part of the Hemp plant as defined above are considered “Hemp Extract” and are subject to Rule 5K- 4.034, FAC.

3. What is the difference between Hemp and Marijuana?

They are both varieties of the *Cannabis* plant, however, Hemp has a Total Δ 9-THC level that does not exceed 0.3% whereas Marijuana has Total Δ 9-THC levels that exceed this amount.

4. What is a “Hemp Food Establishment?”

Any establishment that is engaged in extracting, manufacturing, processing, packing, holding, preparing, or selling Hemp Extract for Human Consumption at wholesale or retail is considered a “Hemp Food Establishment” and is required to have a food permit to operate in Florida.

5. What kind of Hemp Extract products does FDACS Division of Food Safety regulate?

Any product intended for human consumption containing Hemp Extract is regulated by the Division of Food Safety.

HEMP EXTRACT FOR INGESTION AND INHALATION

6. If I already have a food permit with FDACS, what do I need to do to sell Hemp Extract products?

When you apply for your annual food permit, you will be asked if you sell or plan to sell Hemp Extract products intended for human consumption. You must report “yes” on your food permit renewal application and you will be designated as a “Hemp Food Establishment.” If you offer Hemp Extract products after your permit has been issued, you must call the business center at (850) 245-5520 or go online to [FDACS.gov](https://www.fdacs.gov) to update your records. Failure to do so may result in administrative fines.

7. Will my annual food permit fee change if I begin to sell Hemp extract products?

The annual permit fee for Hemp Food Establishments is \$650. If your current food permit fees are less than this, they will increase to \$650.

8. If I do not have a food permit through FDACS, what steps do I need to take?

A food permit application may be submitted online, faxed or mailed to the business center. Please note that faxing or mailing your food permit application will likely result in a delay in the processing of your application. Your facility must also meet the appropriate Minimum Construction Standards (MCS) based on the processing and operations planned for your business. MCS guidance and the food permit application information can be found at [www.FDACS.gov/Divisions-Offices/Food-Safety](https://www.fdacs.gov/Divisions-Offices/Food-Safety). An optional FDACS plan review service is available upon request to review the establishment’s proposed facility layout prior to starting the permitting process.

9. Can businesses that operate under the Cottage Food Laws offer Hemp Extract products?

No. The Cottage Food Laws do not include Hemp Extract and a food permit will be required to extract, manufacture, process, pack, hold, prepare or sell Hemp Extract products. Hemp Extract intended for Human Consumption may not be extracted, manufactured, processed, packed, held, or prepared in a private residence or sold from a private residence.

10. Will I need a food permit if I only sell Hemp Extract products for Human Consumption online and do not store any Hemp Extract products at my physical location?

Yes. A food permit is still required. There are specific labeling requirements under Florida Law and the products are subject to testing by the state’s laboratories. Additionally, online sellers of Hemp Extract products are required to make sure their products are obtained from manufacturers permitted to process Hemp Extract products as required by rule.



HEMP EXTRACT FOR INGESTION AND INHALATION

11. Will I need a special food permit if I want to sell Hemp Extract products intended for Human Consumption from a mobile sales unit?

Mobile food establishments may sell Hemp Extract products so long as they meet the requirements for both mobile food establishments and Hemp food establishments; both of which include being properly permitted.

12. What kind of health claims am I allowed to make for the Hemp Extract that I carry?

Any statement or claim, either on the container itself or on any advertisement for the product, that the Hemp Extract is intended to diagnose, cure, mitigate, treat, or prevent a disease is not allowed. Such claims may result in action (including penalties) taken by FDACS, the U.S. Food and Drug Administration (FDA), and/or the Federal Trade Commission (FTC).

13. What are the labeling requirements for Hemp Extract products such as a bottle that is sold in a sealed box? Are both the bottle and box required to meet the Hemp Extract labeling requirements?

Both the bottle and box must meet the general labeling requirements as shown in Section 1 of the Labeling Guidelines in this document. The Hemp Extract labeling requirements shown in Section 2 only apply to the external container that the consumer will take with them at the time of purchase.

14. How can I verify that the Hemp Extract products that I carry have acceptable levels of Total Δ9-THC?

This is accomplished through laboratory testing. All Hemp Extract products intended for Human Consumption must be accompanied by a lab report called a "Certificate of Analysis." Hemp Extract products may only be distributed and sold in the state if the product has a certificate of analysis prepared by an independent accredited laboratory that states that the batch contained a total delta-9 tetrahydrocannabinol (THC) concentration that did not exceed 0.3 percent and does not contain contaminants unsafe for human consumption, pursuant to the testing of a random sample from the specified batch.



HEMP EXTRACT FOR INGESTION AND INHALATION

15. Where can I get the Certificate of Analysis (COA) for the Hemp Extract products that I carry?

Hemp manufacturers are required to test each batch of Hemp Extract that they produce. If the manufacturer is unable to provide a COA, the Hemp Extract is not in conformance with Florida Law and cannot be sold in this state.

16. Are there any additional storage requirements for Hemp Extract food products?

Hemp Extract must be packaged in containers that minimize exposure to light. To prevent degradation of the cannabinoids, storage at or below room temperature is highly recommended. Without this, the vendor risks non-conformance with labeling requirements following laboratory testing, which can lead to administrative fines if the amount of cannabinoid(s) in the product does not match the lab testing results.

17. What if I find out that a Hemp Extract product that I carry has unacceptable levels of Total Δ 9-THC?

Hemp Extract that exceeds acceptable levels of Total Δ 9-THC must be disposed on in accordance with Rule 5K-4.034(7), Florida Administrative Code.

18. Where can I go to find additional information about Hemp Extract?

You may call the FDACS business center at (850) 245-5520 or go online to www.FDACS.gov/Cannabis/Hemp-CBD-in-Florida for additional information about Hemp Extract in Florida.

Also, please refer to Section 581.217, Florida Statutes, and Rule 5K-4.034, Florida Administrative Code for comprehensive Hemp Extract regulations.

19. Can I sell my Hemp Extract products from a vending machine?

No. Hemp Extract intended for Human Consumption may not be offered for sale by means of vending machines at this time.



HEMP EXTRACT FOR INGESTION AND INHALATION

20. What if my Hemp Extract product could be intended for Inhalation and Ingestion?

Hemp Extract intended for Human Consumption that is not clearly labeled as intended for Inhalation or Ingestion must meet all of the requirements for both Inhalation and Ingestion. In the event that there are different requirements, the stricter standard shall apply.

21. What is considered an acceptable source for my Hemp Extract?

Hemp Extract intended for **Ingestion** must be manufactured by an Approved Source. A valid food license/permit and the most recent food safety inspection report from the Approved Source must be provided to the department upon request.

Hemp Extract intended for **Inhalation** must be manufactured by a source permitted to manufacture Hemp Extract intended for Inhalation. A valid license/permit and the most recent inspection report from the permitting source must be provided to the department upon request.

22. What are the requirements for age limits?

Hemp Extract products intended solely for **Ingestion** are not age restricted at this time.

Products that are intended for human **Inhalation** that contain Hemp Extract may not be sold to a person who is under 21 years of age. Hemp Food Establishments shall require proof of age from a purchaser of any product containing Hemp Extract intended for Inhalation before selling the product to that person.

Any retailer that sells Hemp Extract intended for Inhalation shall post a clear and conspicuous sign directly adjacent to the display of the product which states the following: THE SALE OF HEMP EXTRACT INTENDED FOR INHALATION TO PERSONS UNDER THE AGE OF 21 IS PROHIBITED. PROOF OF AGE IS REQUIRED FOR PURCHASE.

23. Are there any other requirements for selling Hemp Extract intended for Inhalation?

Hemp Extract intended for Inhalation shall not be offered for sale by means of self-service merchandising unless proof of age has been verified before allowing access to the self-service merchandising. Please note that “self-service merchandising” is not a “vending machine.”

Additionally, Hemp Extract intended solely for Inhalation must be clearly labeled with the statement “Not Intended For Ingestion - Do Not Eat.” Any Hemp Extract products not labeled in this manner must be safe for human consumption by means of ingestion or inhalation.



HEMP EXTRACT LABELING GUIDELINES

INGESTION

1. Existing labeling requirements for packaged products include the following:

- The identity of the product (this is not the same as the brand name).
- A list of ingredients (including sub-ingredients) in order of abundance.
- The business name and address of the manufacturer, packer, or distributor (also referred to as the Responsible Party).
- An accurate declaration of the quantity of the net contents in both SI and U.S. Customary units, such as milliliters (ml) and fluid ounces (fl. oz).
- A Nutrition Facts panel, unless exempt.
- Servings per container and the serving size.
- The label, and advertisement, shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease rendering it a drug as defined in 21 U.S.C. 321(g)(1).

2. In addition to the above requirements, Hemp Extract intended for human consumption must be distributed and sold in a container that includes:

1. A scannable barcode or quick response code linked to the certificate of analysis of the hemp extract by an independent testing laboratory,
2. The batch number,
3. The internet address of a website where batch information may be obtained,
4. The expiration date,
5. The number of milligrams of each marketed cannabinoid per serving.



Nutrition Facts		Amount/serving		% Daily Value*	Amount/serving		% Daily Value*
30 servings per container		Total Fat 1g		1%	Total Carbohydrate 0g		0%
Serving size 1 dropperful (1mL)		Saturated Fat 1g		5%	Dietary Fiber 0g		0%
Calories per serving		Trans Fat 0g			Total Sugars 0g		
		Polyunsaturated Fat 1g			Includes 0g Added Sugars		0%
		Monounsaturated Fat 0g			Sugar Alcohol 0g		
		Cholesterol 0mg		0%	Protein 0g		0%
		Sodium 0mg		0%			
		Vitamin D 0mcg	0%	Calcium 0mg	0%	Iron 0mg	0%
		Potassium 0mg	0%				

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(Labels for example purposes only.)

HEMP EXTRACT LABELING GUIDELINES

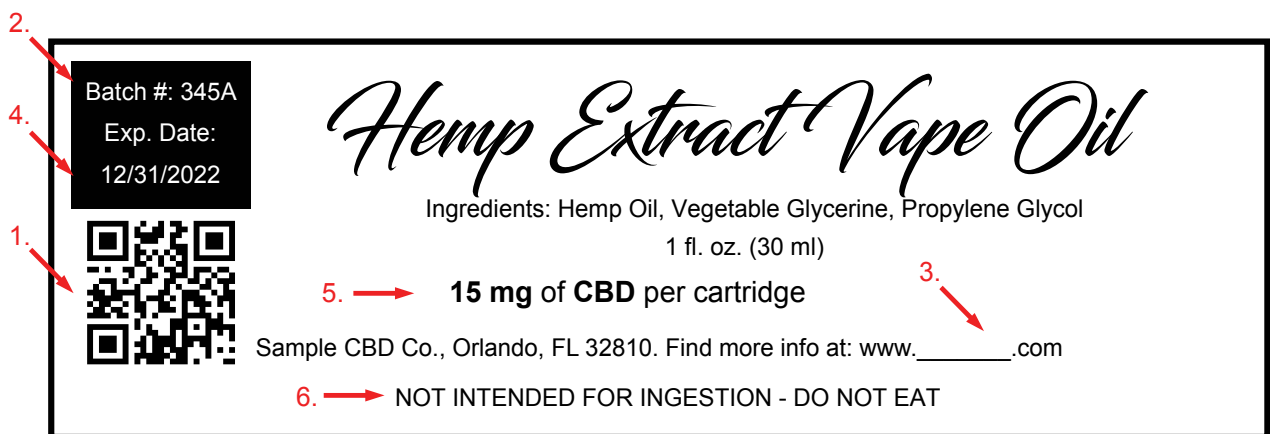
INHALATION

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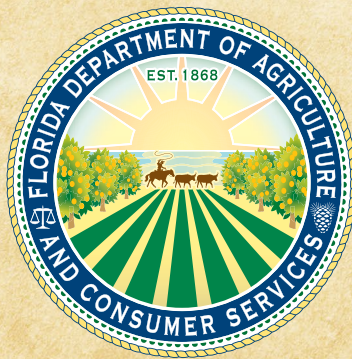
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4. The expiration date,
5. The number of milligrams of each marketed cannabinoid per serving/container,
6. The statement “Not Intended for Ingestion - Do Not Eat”.



(Label for example purposes only.)



Questions about Hemp?

For additional information, visit our website:
FDACS.gov/Cannabis/Hemp-CBD-in-Florida

